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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., WARNER-LAMBERT COMPANY LLC, GÖDECKE GMBH, and PFIZER PHARMACEUTICALS LLC,	)	MDL No. 1384
	)	Master Docket No. 00-CV-2931 (FSH)
Plaintiffs,	)	
	)	**This Filing Applies To:**
v.	)	Purepac Defendants
	)	C.A. No. 00-CV-2931 (FSH)
PUREPAC PHARMACEUTICAL CO., FAULDING INC., and ACTAVIS ELIZABETH LLC,	)	C.A. No. 00-CV-3522 (FSH)
Defendants.	)	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO STRIKE CERTAIN AFFIRMATIVE DEFENSES AND TO DISMISS CERTAIN COUNTERCLAIMS OF PUREPAC DEFENDANTS

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PRELIMINARY STATEMENT

Purepac's opposition brief ("Purepac Br.") confirms that, even accepting all of its allegations as true, Purepac cannot establish key elements of its antitrust claims. Most importantly, Purepac cannot establish that it has suffered any injury at all, let alone any injury cognizable by the antitrust laws, or that many of W-L's alleged acts of which it complains are not subject to *Noerr-Pennington* immunity. Purepac's brief further confirms that Purepac's allegations do not state a patent misuse or unclean hands defense.[1] Because there is no legal basis for these claims and defenses they should be dismissed.

First, Purepac cannot show antitrust injury because it made the business decision not to launch its generic products for at least 17 months after the last alleged W-L "roadblock" was lifted and for 13 months after it received final FDA approval. Purepac tries to justify its own business decision not to launch by pointing to its litigation with Apotex over Purepac's right of exclusivity ("the FDA litigation") which it contends created uncertainty for it. That argument fails

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[1] Purepac cannot show that W-L's alleged off-label marketing is closely related to its claim for infringement of the '482 Patent, as required for unclean hands, or that a mere shift in the start and end dates of a 17-year patent term constitutes a physical or temporal extension of the '482 Patent as required for patent misuse. In light of the factual and legal similarity between Purepac's patent misuse and unclean hands arguments and those of Teva, IVAX, and Eon, W-L addresses Purepac's patent misuse and unclean hands defense and counterclaim in its reply brief in support of its motion to strike certain affirmative defenses of Teva, IVAX, and Eon Defendants, and incorporates those arguments by reference herein.

because the FDA litigation did not block Purepac's market entry and W-L was not involved in or responsible for it. Moreover, Purepac's attempt to hold W-L responsible for that litigation would necessarily require Purepac to show that W-L could have foreseen in 1994 when it filed its patent notification statement for its '476 and '479 Patents with the FDA that Purepac and Apotex would file ANDAs, the timing of those filings relative to each other, and that Purepac and Apotex would have a dispute over priority years later in the courts that would purportedly delay generic entry beyond the expiration of any 30-month stay. Of course Purepac pleads no such thing. Therefore, Purepac cannot show that any of W-L's alleged acts was the proximate cause of Purepac's allegedly delayed launch.

Purepac also cannot deny that the alleged W-L imposed "roadblocks" were not roadblocks at all to Purepac's market entry. Rather, Purepac's market entry was legitimately and legally blocked by operation of the '544 Patent (which Purepac never challenged), the stay relating to the '482 Patent (which issued during the extended period of pediatric exclusivity of the '544 Patent), and its own lack of tentative approval from the FDA. Thus, Purepac cannot show that its market entry was affected in any way by the listing of, or litigation concerning, the '476 and '479 Patents. Indeed, far from being injured, Purepac cannot dispute that it profited greatly from its at-risk launch, in a way that would not have been

possible had W-L not listed the '482 Patent in the Orange Book when it did.[2]

Purepac tries to salvage its antitrust counterclaims by arguing that it has somehow alleged an "overall scheme" to monopolize, but Purepac's argument runs headlong into established authority that individual acts that are authorized by law cannot nonetheless add up to an antitrust violation. And Purepac cannot establish that any of W-L's alleged predicate acts was unlawful.

First, Purepac cannot show that W-L's alleged actions in delaying the prosecution of the '482 Patent were not protected by *Noerr-Pennington* immunity. Purepac admits that it has not pled *Walker Process* fraud. Moreover, Purepac's allegations concern the outcome of the process – the issuance of the '482 Patent and subsequent litigation that triggered a 30-month stay. The outcome of that process, however, is not actionable for it is nothing other than W-L's lawful exercise of its '482 Patent rights.

Second, even if the Court were to consider Purepac's allegations concerning the listing of the '476 and '479 Patents, which it should not, Purepac cannot establish that W-L's listing was unreasonable in light of the recognition by this Court and others of the uncertainty and legitimate debate at the time over the interpretation of the listing regulations then in effect. *See, e.g., Organon v. Mylan*

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[2] Purepac was deemed to be the first ANDA filer with respect to the '482 Patent, entitling Purepac to 180 days of exclusivity. Purepac would not have had this period of exclusivity from which it richly profited but for W-L's listing of the '482 Patent in the Orange Book.

Pharm., Inc., 293 F. Supp. 2d 453, 460 (D.N.J. 2003). Purepac also falls far short of establishing that *Noerr-Pennington* immunity does not bar its sham litigation claims with respect to the '476 and '479 Patents because several courts have already ruled that the infringement claims asserted in those actions were not objectively baseless. These rulings preclude any finding here that ***no reasonable litigant*** could have expected to prevail in those litigations. *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ("*PRE*").[3]

For the reasons stated herein, as well as in W-L's opening brief on the motions to dismiss and strike ("Pls. Br.") and W-L's reply brief on its motion to strike certain affirmative defenses of Teva, Ivax, and Eon Defendants, incorporated by reference herein, Purepac should not be permitted to further prolong this already extended litigation by engaging in extensive discovery into facts which have nothing to do with the patent infringement issues and which, even if true, do not state a claim or defense. W-L respectfully requests that Purepac's counterclaims be dismissed and its third affirmative defense be stricken.

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[3] Purepac's only response to the rulings W-L cites from this and other courts on these issues is to contend that they are wrong. *See* Purepac Br. at 32 (arguing that the Court's decision in *Organon* is incorrect with respect to reasonableness of interpretation of 21 C.F.R. § 314.53(b)); *id.* ("Purepac respectfully submits that Judge Schall misinterpreted 21 C.F.R. § 314.53(b)."); *id.* at 36 (stating that "Judge Lifland improperly decided disputed issues of material fact" related to reasonableness of litigation claims).

ARGUMENT

I. PUREPAC'S UNCLEAN HANDS AND PATENT MISUSE DEFENSE SHOULD BE STRICKEN AND ITS COUNTERCLAIM DISMISSED.

W-L incorporates by reference the arguments set forth in its reply brief in support of its motion to strike certain affirmative defenses of Teva, Ivax, and Eon Defendants, filed herewith, in support of its motion to dismiss Purepac's unclean hands and patent misuse counterclaim and to strike its related third affirmative defense.

Purepac asserts that its unclean hands and patent misuse counterclaim should not be dismissed because Purepac purportedly meets the requirements for declaratory judgment relief under *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007). *See* Purepac Br. at 18. The Federal Circuit has held, however, that "[t]he Declaratory Judgment Act neither expands a court's jurisdiction nor creates new substantive rights." *B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1428 (Fed. Cir. 1997) (citing 12 James Wm. Moore *et al.*, *Moore's Federal Practice* § 57.02[1] (3d ed. 1997)). The Federal Circuit has held that "[n]o case law from the Supreme Court or this court provides a basis for nullifying property rights granted by the United States when such property rights did not themselves accrue through inequitable conduct." *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1377-78 (Fed. Cir. 2001) (further holding that "the doctrine of unclean hands [does not] provide a suitable basis for the trial court's [holding of

unenforceability], as this equitable doctrine is not a source of power to punish"); *see also* Pls. Br. at 23. Yet Purepac does not plead inequitable conduct. Purepac cannot rely upon the Declaratory Judgment Act to create a substantive right – a declaration that the '482 Patent is unenforceable – where there is none under existing case law.

Nor can Purepac distinguish *Aptix* on the basis that the *Aptix* court considered unclean hands in the context of litigation misconduct. If fraud upon the district court during litigation does not suffice to support a declaration of unenforceability based on unclean hands, then, *a fortiori*, W-L's alleged marketing violations years before this suit was filed likewise would not support such relief. And because "the patent misuse doctrine is an extension of the equitable doctrine of unclean hands," *B. Braun*, 124 F.3d at 1427, the Court likewise lacks the power to grant a declaration of unenforceability due to patent misuse in the absence of inequitable conduct.

II. PUREPAC'S ANTITRUST COUNTERCLAIMS SHOULD BE DISMISSED FOR FAILURE TO SHOW ANTITRUST INJURY.

A. Purepac's Failure to Launch Prevents Purepac From Showing Antitrust Injury.

As W-L showed in its opening brief, the last alleged "roadblock" in any conceivable antitrust scheme Purepac alleged was lifted as of May 2003. Pls. Br. at 26-27. Yet Purepac waited another 17 months – and 13 months after it

received final FDA approval in September 2003 – before it launched its gabapentin capsule products in October 2004. *See* Pls. Br. at 27. An antitrust plaintiff must show that the alleged acts were the proximate cause of its injury. *See Assoc. Gen. Contractors of Cal. v. Cal. State Council of Carpenters*, 459 U.S. 519, 540 (1983). As a matter of law, Purepac cannot show injury-in-fact because it cannot show proximate causation. *See Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 865 (D.C. Cir. 2008) (affirming summary judgment where plaintiffs could not show that Andrx could have gone to market with its generic drug product but for the assertion of the patent in suit). Because of its self-imposed delay, Purepac cannot show what it must to establish antitrust injury, namely, that it "intended and was prepared to enter the market." *Id.* at 862 (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 126-29 (1969)).

Recognizing that its own business decision to delay its launch precludes it from showing that W-L's alleged acts was the proximate cause of its injury, Purepac seeks to justify its decision to delay by making new factual allegations in its brief suggesting that W-L is responsible for its FDA litigation with Apotex. Of course, Purepac's last minute attempt to inject new allegations into its brief is improper. *Delaware Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1284 n.1 (D. Del. 1995) ("Facts . . . raised by counsel for the first time in a legal memorandum, are not properly considered by the Court when deciding a Rule 12(b)(6) motion. The Court must limit its consideration to the facts alleged in

the complaint."), *aff'd*, 141 F.3d 1153 (3d Cir. 1998). In any event, Purepac's new allegations do not change the dispositive fact that Purepac's own business decision to delay its launch breaks any alleged chain of causation.

The fact that Purepac cannot establish any chain of causation between W-L's allegedly wrongful acts and Purepac's delayed market entry is highlighted by the fact that Purepac has to reach back to acts that happened in 1994 – W-L's filing of its patent notification statement for its '476 and '479 Patents with the FDA – to come up with predicate acts for its alleged antitrust violations. And to support its new attempt to hold W-L responsible for the FDA litigation, Purepac necessarily must show that W-L somehow should have anticipated in 1994 that its decision to list certain patents would cause a priority dispute in the FDA approximately a decade later that purportedly would delay generic entry beyond the expiration of any 30-month stay. To state the proposition is to refute it. Of course, W-L had no control over the generics' ANDA filings, the timing of those filings relative to each other, the litigation that subsequently arose over them, or how the federal courts would decide those disputes. And Purepac does not contend otherwise. Purepac also has not alleged that W-L's listing of the '482 Patent was not reasonable – nor could it, given that it was this listing that afforded Purepac 180 days of exclusivity over other ANDA filers.

Purepac also points to the two-month stay that the court imposed in the FDA litigation in the summer of 2004 and complains that, had Purepac

launched earlier, which it admittedly was free to do, the stay "would have compromised Purepac's 180-day exclusivity had Purepac been on the market at the time." Purepac Br. at 8. W-L was not responsible for either the two-month stay the court imposed (which only accounts for two of the 17 months Purepac delayed its launch), or Purepac's business decision not to risk losing out on a portion of its extremely profitable period of exclusivity – which it obtained only because of W-L's listing of the '482 Patent in the Orange Book.

Even if W-L were somehow responsible for the FDA litigation, which it was not, that litigation did not prevent Purepac from launching its product. Purepac admits it could have launched, but asserts (again in its brief, not in its pleading) that it "did not launch earlier because that would have meant that Purepac not only had to risk liability for infringement of the '482 Patent, but also the possibility that its approval would have been revoked after entering the market." Purepac Br. at 8. *See also id.* at 40 ("An earlier launch meant Purepac had to accept the possibility of a court-ordered revocation of marketing ability and risk losing a portion of its 180-day generic exclusivity."). Indeed, the fact that Purepac launched its capsule products in October 2004 in the face of that uncertainty – before Apotex's appeal was decided in December 2004 – demonstrates conclusively that the FDA litigation did not block Purepac's market entry. *See Apotex, Inc. v. FDA*, 393 F.3d 210 (D.C. Cir. 2004).

In any event, the risk of infringement of the '482 Patent is – by definition – not antitrust injury. If Purepac infringed, then W-L had the right to exclude it from that market. *See In re Indep. Serv. Org. Antitrust Litig.*, 989 F. Supp. 1131, 1141 (D. Kan. 1997) ("The patent statute expressly grants patent holders the right to exclude others from manufacturing, selling, or using their invention.") (citing 35 U.S.C. § 154). Furthermore, had the court in the FDA litigation revoked Purepac's marketing approval, that holding would have been based on a finding that Purepac was not entitled to 180 days of generic exclusivity as the first ANDA filer. Such a finding would have nothing to do with W-L. That is not a harm for which W-L can be held liable, or one which the antitrust laws were intended to redress.

Purepac inexplicably cites *Dr. Reddy's Laboratories, Ltd. v. AAIPharma, Inc.*, 2002 WL 31059289, at *10-11 (S.D.N.Y. Sept. 13, 2002), for the proposition that "FDA inquiries delaying an ANDA applicant's market entry d[oes] not break the chain of causation . . . where the improper conduct was alleged to have caused the FDA to make inquiries." Purepac Br. at 40. This case is factually and legally inapposite. In *Dr. Reddy's*, aaiPharma claimed that Dr. Reddy's Laboratories ("DRL") had not pled any harm caused by aaiPharma because DRL's market entry was delayed by the FDA's requirement that DRL perform additional testing of its product. The pleadings alleged, however, that the additional testing was the result of a co-conspirator's (AstraZeneca)

misappropriation of DRL's data concerning the bioequivalency of DRL's product to AstraZenaca's product, and the inappropriate forwarding of such data to the FDA to argue that the product was not bioequivalent. The court concluded that the allegations "sufficient[ly] plead DRL's alleged injury, notwithstanding the fact that aaiPharma does not have control over the FDA." *Id.* at *11. Plainly there is no comparable conduct alleged here. Here, it was a dispute between competing ANDA filers as to priority – and not any act by W-L – that triggered the FDA's involvement. Further, unlike in *Dr. Reddy's*, Purepac was not blocked from entering the market. Purepac alone made the decision not to launch when it could have, because it concluded that the risks were just too high.

In fact, *Dr. Reddy's* only highlights the insufficiency of Purepac's allegations. The court's decision appears to turn primarily on the issue of whether DRL sufficiently pled proximate cause (*id.* at *10-11), *i.e.*, whether it was foreseeable that the harm would have directly resulted from the alleged misconduct. Here, in contrast, Purepac has not, and cannot, allege that W-L should have foreseen that its decision to list certain patents in the Orange Book would cause a priority dispute between Purepac and Apotex many years later that allegedly would delay generic entry beyond any applicable 30-month stay. Also nothing in *Dr. Reddy's* suggests that the chain of causation is not broken where a party fails to launch for its own business reasons, as Purepac admittedly did.

Eli Lilly & Co. v. American Cynamid Co., 2001 WL 30191, at *5 (S.D. Ind. Jan 1, 2001), which Purepac cites, likewise is distinguishable. There, Zenith complained that its market entry was delayed because Lilly had tied up nearly all of its potential bulk suppliers. The only remaining supplier, Opos, did not have an approved Abbreviated Antibiotic Drug Application ("AADA"). Lilly argued that the FDA's slow approval of Opos's AADA was the real cause for Zenith's delayed market entry. The court disagreed, ruling that because Zenith had pled that it would have used another bulk supplier – one that Lilly had tied up – "[t]here is, then, at least one set of facts which, if proved, will demonstrate that Zenith was injured by Lilly's alleged actions." *Id.* Here, in contrast, it was Purepac's own decision, and not W-L's alleged acts, that caused its delayed launch. The lack of any proximate causation thus cuts off Purepac's claim of antitrust liability.

B. Purepac Also Cannot Show Antitrust Injury Because Purepac's Market Entry Was Legitimately and Legally Blocked By The '544 and '482 Patents, As Well As By Its Lack Of Tentative Approval To Market Its Products.

Purepac also cannot show that it suffered any legally cognizable antitrust injury because Purepac's market entry was blocked by the '544 and '482 Patents. *See* Pls. Br. at 33-34. Specifically, Purepac was legitimately and legally blocked from entering the market by the '544 Patent (which Purepac never challenged) until July 2000 when the period of pediatric exclusivity expired. Prior

to the expiration of that period, the '482 Patent issued in April 2000. W-L listed that patent, and following Purepac's paragraph IV certification, W-L filed this litigation, commencing a 30-month stay that extended until December 2002. Purepac does not contend that either the '482 Patent listing was improper, or that this litigation was sham.[4] Thus, even accepting as true Purepac's allegations that the listing of, or litigation concerning, the '476 and '479 Patents was improper, Purepac could not have been harmed by the 30-month stay based on these patents because Purepac was already blocked from entering the market due to the '544 and '482 Patents. Purepac's inability to enter the market by operation of these patents renders all the conduct Purepac alleges in its amended counterclaim irrelevant and breaks any chain of causation between W-L's alleged wrongful acts and Purepac's purportedly delayed market entry. *See Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111-2 (6th Cir. 1989) (affirming dismissal after finding that plaintiff was excluded

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[4] Purepac's argument concerning the timing of the '482 Patent depends entirely on the allegation that W-L improperly shifted the start and end dates of the term of the '482 Patent by withdrawing the patent from issue to cite additional art to the Examiner. For the reasons set forth in W-L's concurrently filed reply brief on its motion to strike certain affirmative defenses of Teva, Ivax, and Eon Defendants, such a delay does not constitute patent misuse and is not actionable as a matter of law. As discussed, *infra*, the alleged delay in prosecution also cannot be the predicate for antitrust liability because such activities are protected by *Noerr-Pennington* immunity.

from the market by defendant's patents rather than by the allegedly anticompetitive conduct). ***Notably, Purepac did not even respond to this in its opposition.*** [5]

Purepac also cannot show that it would have entered the market earlier but for W-L's alleged wrongful acts because Purepac did not have tentative FDA approval at any time during the 30-month stay associated with the '476 Patent (and under the FDA's interpretation, with the '479 Patent) that ended in December 2001. *See* Ans. at 39, ¶ 101. Several courts have held that this fact alone cuts off proximate causation. *See* Pls. Br. at 32 (citing *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004), and *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 25 (D. Mass. 2000)). Purepac cites to two cases where courts reached different conclusions – *Bristol-Myers Squibb Co v. Ben Venue Labs.*, 90 F. Supp. 2d 540 (D.N.J. 2000),

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[5] Purepac also does not deny Purepac's improper listing argument was premised on an erroneous factual allegation. *See* Purepac Br. at 26, 30. As W-L noted, Purepac pled that W-L's original motivation for listing the '476 and '479 Patents in the Orange Book in early 1995 was "as a stopgap to prevent generic competition" (*see* Ans. at 44, ¶ 123). As Purepac pled:

> Knowing that the '544 patent was due to expire in May 1995, and with the requested patent-term extension on the '544 patent still pending, and with the need to withdraw the '270 application, Warner-Lambert had a choice: list additional patents in the Orange Book that it knew did not cover Neurontin® or run the risk that the Patent Office would deny the patent-term extension allowing generic entry as early as May 1995.

W-L demonstrated that in fact, W-L had filed its patent notification statement with respect to the '476 and '479 Patents in January 1994, and thus that Purepac's allegation was without basis.

and *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751 (E.D. Pa. 2003) – but ignores W-L's explanation in its opening brief of why those cases are entirely distinguishable. *See* Pls. Br. at 32 n.11.

III. PUREPAC'S ALLEGATIONS OF AN "OVERALL SCHEME" FAIL AS A MATTER OF LAW.

Rather than even attempting to counter W-L's arguments that the acts it has alleged were not unlawful, Purepac throws up a smokescreen by arguing that W-L has improperly "compartmentalize[d] Purepac's allegations . . . , arguing that each individual act is not actionable" when the "anticompetitive effects and legality of the alleged monopolization scheme must be evaluated as a whole." Purepac Br. at 20. Despite citing its shorthand shibboleth of "overall monopolization scheme" again and again, Purepac cannot state an antitrust claim where, as here, each of the alleged wrongful acts was *expressly authorized by law*. *See In re Indep. Serv. Org. Antitrust Litig.*, 989 F. Supp. 1131, 1141 (D. Kan. 1997) ("None of the authorities cited by CSU discuss whether conduct *expressly authorized by law* may be transformed into unlawful conduct if such acts are part of a scheme to monopolize.") (emphasis in original). *See also Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1366-67 (Fed. Cir. 1999) ("*Continental Ore* [*Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690 (1962)] did not hold . . . that the degree of support for each legal theory should be added up. Each legal theory must be examined for its sufficiency and applicability, on the entirety of the

relevant facts."). Simply put, aggregating lawful conduct does not make it unlawful.

Purepac's argument that an allegation of an overall scheme can overcome the fact that each of the component acts is, on its own, not actionable, rests on its faulty reading of *In re Remeron Antitrust Litigation*, 335 F. Supp. 2d 522, 528 (D.N.J. 2004) (which in turn quotes *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003)), *Continental Ore*, 370 U.S. at 699, *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 44 (D.D.C. 2000), and *Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1522 n.18 (10th Cir. 1984), *aff'd*, 472 U.S. 585 (1985). In each of these cases, the party's individual conduct violated the antitrust laws. *See In re Indep. Serv. Org. Antitrust Litig.*, 989 F. Supp. at 1141-42. For example, *Remeron* involved the late listing of a patent in the Orange Book in violation of regulatory requirements (335 F. Supp. 2d at 532); *LePage's* involved two types of illegal exclusionary conduct, "exclusive dealing arrangements" and "bundled rebates" (324 F. 3d at 154, 157); *Continental Ore* involved an illegal group boycott (370 U.S. at 698-99); and *Aspen Highlands* involved a refusal to include a competitor's product in a package offering (*see Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985)).

Another case that Purepac cites, *United States v. Microsoft Corp.*, 87 F. Supp. 2d at 44 (affirmed in part and reversed in part in *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001)), likewise involved individual

conduct that was independently actionable. Although Purepac correctly quotes the court as stating that "the full extent of the violence" could only be seen "when the separate categories of conduct are viewed . . . as a single, well-coordinated course of action" (Purepac Br. at 21 n.5), it omits the prior sentence where the court also stated that "Microsoft's campaign to protect the applications barrier from erosion by network-centric middleware can be broken down into discrete categories of activity, several of which *on their own independently* satisfy the second element of a § 2 monopoly maintenance claim." *Microsoft Corp.*, 87 F. Supp. 2d at 44 (emphasis added).

Here, as W-L demonstrated in its opening brief, none of the alleged misconduct – either individually or collectively – violates the antitrust laws. *See In re Indep. Serv. Org. Antitrust Litig.*, 989 F. Supp. at 1142 ("Conduct expressly authorized by one law or governmental agency cannot be simultaneously subject to antitrust scrutiny."). *See id.* at 1142 ("[A]llowing a plaintiff to combine a defendant's lawful and unlawful activities effectively would eliminate the requirement that an antitrust plaintiff must show a 'causal connection between the [defendant's] antitrust violations and [plaintiff's] injury.'") (citing, *inter alia*, *Continental Ore Co.*, 370 U.S. at 700).

Thus, Purepac's attempt to lump together otherwise lawful conduct to state an antitrust claim must fail. Purepac's "obligation to provide the 'grounds' of [its] 'entitle[ment] to relief' requires more than labels and conclusions, and a

formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1964-65 (2007). Because Purepac has not identified any anticompetitive conduct cognizable under the antitrust laws, it cannot combine that lawful conduct to create an "overall scheme" to monopolize.

IV. PUREPAC'S PROSECUTION DELAY, LISTING, AND SHAM LITIGATION CLAIMS FAIL AS A MATTER OF LAW.

A. Purepac Cannot Show That W-L's Prosecution of the '482 Patent Is Not Petitioning Activity Protected By the *Noerr-Pennington* Doctrine.

Purepac does not dispute that prosecution of a patent application in the Patent Office is protected by *Noerr-Pennington* immunity. Purepac attempts, however, to argue that, even though it admittedly does ***not*** plead *Walker Process* fraud on the Patent Office, it has some other basis for asserting that *Noerr-Pennington* immunity does not apply to W-L's prosecution of the '482 Patent. "To be clear, Purepac does not assert in its antitrust counterclaims that the '482 patent should not have issued because of fraud on the Patent Office. Rather, Purepac takes issue with W-L's abuse of the Patent Office." Purepac Br. at 24. Purepac then argues that a "pattern of baseless repetitive claims may emerge which leads the fact finder to conclude that the administrative and judicial processes have been abused." Purepac Br. at 21 (citing *California Motor Trans. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972) (internal quotations omitted)).

The cases Purepac cites, however, all involved situations, unlike here, where a party used the process itself – rather than the outcome of it – as an anticompetitive weapon. In *California Motor Transport*, for example, the petitioner was alleged to have schemed to deny respondents "free and unlimited access" to courts and administrative agencies by overwhelming them with baseless litigation with the purpose of "'discourag[ing] and ultimately . . . prevent[ing] the respondents from invoking' the processes of the administrative agencies and courts." 404 U.S. at 511-512. Here, W-L plainly did not block Purepac's access to the Patent Office. Nor does Purepac contend that W-L committed inequitable conduct in its dealings with the Patent Office. And far from W-L's conduct being baseless, the Examiner found that W-L's claims were patentable over the cited art. In short, W-L properly pursued its patent application in the Patent Office, as was its right: "Multiple interviews are not illegal, and persistence in patent prosecution is not grist for patent invalidity." *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997). W-L's persistence paid off when the Patent Office allowed the '482 Patent to issue in 2000.

Further nothing W-L did during the prosecution of the '482 Patent blocked Purepac, and Purepac does not and cannot allege that it did. Although Purepac throws around the words "inequitable conduct," it does not even purport to assert such a defense, which requires a showing that W-L made material misrepresentations or omissions with intent to deceive the Patent Office. As W-L

pointed out in its opening brief (Pls. Br. at 29-30), rather than omitting relevant art, W-L withdrew its patent from issue to allow the Patent Examiner to consider art which Purepac admits was "material." Ans. at 21, ¶ 40. *See Kimberly-Clark Corp. v. Procter & Gamble Distributing Co., Inc.*, 973 F.2d 911 (Fed. Cir. 1992) (finding no intent to deceive where prior art was not immediately, but later disclosed to the Patent Office).

Here, it is the outcome of the process – the issuance of the '482 Patent – and not the process itself that allegedly blocked Purepac. As Purepac itself alleges (Ans. at 43, ¶ 119):

> Warner-Lambert's slow pace in prosecuting the '618 application . . . allowed Warner-Lambert to time the issuance and listing of the '482 patent to gain, albeit improperly, a "second" 30-month stay on FDA approval of Purepac's ANDAs, and thus delay the eventual launch of Purepac's generic gabapentin products.

Because Purepac does not and cannot challenge the '482 Patent listing or contend that the suit under the '482 Patent was baseless, it cannot complain about the resulting outcome – a statutory 30-month stay of its launch.

Finally, Purepac argues that in *DiscoVision Assoc. v. Disc Manufacturing, Inc.*, 1997 WL 309499 (D. Del. Apr. 3, 1997), "abuse of process and inequitable conduct before the Patent Office identical to those Purepac has alleged here have been found to state a claim for monopolization before." Purepac Br. at 25. That simply is not correct. *DiscoVision* involved allegations that the

patentee had made "misrepresentations and misleading statements" to the PTO and "withheld material prior art," culminating in "fraudulently obtained patents." 1997 WL 309499, at *8. Purepac admits that it has not alleged any of these things.

B. Purepac Cannot Show That the Listing of the '476 and '479 Patents Was Unreasonable.

As noted earlier, the Court need not reach the issue of whether the listing of the '476 and '479 Patents was reasonable because Purepac was blocked from entering the market due to the operation of the '544 Patent, the 30-month stay resulting from the '482 Patent litigation, and Purepac's lack of tentative FDA approval during the time the '476 and '479 Patent stays were in effect. *See* Argument II.B., *supra*. To the extent the Court nonetheless reaches these issues, Purepac cannot establish that W-L's listing of those patents in the Orange Book was unreasonable. That is because the FDA itself and several courts have recognized that there was legitimate dispute and uncertainty at the time over the interpretation of the listing regulations then in effect.

With respect to the '476 Patent, this Court has acknowledged that the Hatch-Waxman Act provisions in effect were reasonably interpreted to *require* W-L to list any "patent that claims the *drug* for which [W-L submitted its NDA]." 21 U.S.C. § 355(b)(1) (emphasis added). *See Organon, Inc. v. Mylan Pharm., Inc.*, 293 F. Supp. 2d 453, 460 (D.N.J. 2003). Here, gabapentin is the active pharmaceutical ingredient in Neurontin® and the drug claimed in the '476 Patent.

The fact that they use different polymorphs of the drug (gabapentin anhydrous for Neurontin® and gabapentin monohydrate for the '476 Patent) did not render those regulations inapplicable. The FDA itself recognized in 2003 that there had been "legitimate confusion" about whether polymorph patents had to be submitted for listing in the Orange Book, arising from "certain court decisions, [the FDA's] response to those court decisions, and other public statements." 68 Fed. Reg. 36,676, 36,678 (June 18, 2003). Given that the FDA itself found its rules confusing, Purepac cannot show that it was unreasonable, prior to 2003, for a NDA holder to submit a hydrate polymorph patent for listing.

With respect to the '479 Patent, Purepac argues that W-L's listing was improper because FDA regulations "only permitted listing patents covering approved methods of use," and the use covered by the '479 Patent (neurodegenerative diseases) had not been approved by the FDA. Purepac Br. at 30. The *Organon* court, however, expressly determined that the statute's "clear language" "***required***" a NDA holder to "provide patent information for listing in the Orange Book for *any* patent which claims a method of using the approved drug that is issued after the NDA is approved, not only approved uses." *Organon,* 293 F. Supp. 2d at 460 (*citing* Judge Schall's concurring opinion in *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1338-39 (Fed. Cir. 2003)) (emphasis added). Purepac's argument to the contrary rests entirely on its assertion that this Court's ruling and Judge Schall's concurrence were wrong. *See* Purepac Br. at 32 (arguing

that Judge Schall misinterpreted 21 C.F.R. § 314.53(b) in stating that the regulation was fairly interpreted as requiring listing of all uses of a drug).

This Court's rulings are controlling and dispositive, however. The fact that this Court has held that the FDA's patent listing regulation, 21 C.F.R. § 314.53 (2002), could not lawfully be read as limiting listing eligibility to those patents that claimed only FDA-approved uses, whether rightly or wrongly decided, demonstrates as a matter of law that it would not have been unreasonable for a NDA holder to adopt such an interpretation of the statute. *See Organon,* 293 F. Supp. 2d at 460; *Allergan,* 324 F.3d at 1339 (citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 484 (2001)).

Purepac asserts that *Organon* is distinguishable because Purepac's claim is "part of an overall monopolization claim" and because "while Organon perhaps reasonably misinterpreted the FDA regulations given its circumstances, *id.* at 460, Warner-Lambert actually understood very well what the FDA regulations required of it but strategically ignored them." Purepac Br. at 32. As noted above, however, Purepac cannot seek to impose antitrust liability for otherwise lawful acts by alleging an "overall scheme." As to the latter point, the allegations in *Organon* were no different. As the Court explained:

> The Defendants further allege that Organon, by ***knowingly*** submitting an improper listing of the '099 patent to benefit from the thirty-month stay of the FDA's approval of their ANDAs, effectively employed the statutory process in bad faith to extend its control over

> the mirtazpine market, thereby perpetuating a monopoly in violation of the Sherman Act.

293 F. Supp. 2d at 459 (emphasis added). Despite these allegations, the Court concluded as a matter of law on a motion to dismiss that "given the statutory and regulatory language at the time it submitted [the patent in question] for listing in the Orange Book, Organon had a reasonable basis for the submission, and therefore, Organon's listing was not improper." *Id.* at 460. Furthermore, the patent in *Organon* – just like the '479 Patent here – claimed an unapproved method of treating a disease, namely the use of the NDA drug in conjunction with a second drug, where the only approved method was the use of the NDA drug alone (monotherapy). *Organon*, 293 F. Supp. 2d at 460. *Organon* is squarely on point.

C. Purepac's Sham Litigation Claims Are Also Without Merit.

Purepac admits that W-L's '476 and '479 Patent lawsuits are subject to *Noerr-Pennington* immunity unless Purepac can show they were sham. But, Purepac attempts one more stalling tactic: it argues that "sham-litigation claims cannot be resolved upon a 12(b)(6)" motion where, as here, W-L's state of mind at the time of the filing is a disputed question of fact. *See* Purepac Br. at 33-34. In short, Purepac argues that it needs discovery before this Court can finally rule on the issue of whether the litigations brought with respect to the '476 and '479 Patents were "sham."

This argument directly contradicts the Supreme Court's *PRE* holding that litigation cannot be sham, regardless of subjective motivation or intent, where the filing was ***objectively reasonable***:

> We left unresolved the question presented by this case – whether litigation may be sham merely because a subjective expectation of success does not motivate the litigant. ***We now answer this question in the negative*** and hold that ***an objectively reasonable effort to litigate cannot be sham regardless of subjective intent***.

508 U.S. at 57 (emphasis added).

Thus, contrary to Purepac's claim that it needs discovery, the first prong of *PRE* is a question of law: was W-L's litigation "*objectively* baseless"? *See id.* at 63 ("Where, as here, there is no dispute over the predicate facts the underlying legal proceeding, a court may decide probable cause as a matter of law."). The Supreme Court in *PRE* affirmed a denial of a similar request for discovery by PRE, stating: "As we have held, PRE could not pierce Columbia's *Noerr* immunity without proof that Columbia's infringement action was objectively baseless." *Id.* at 65.

In a blatant overstatement, Purepac argues that Judge Lifland previously ruled that Purepac "clearly state[d] a claim for sham litigation" based on its allegations that W-L filed the earlier litigation without an objective basis and despite receiving conclusive evidence of noninfringement. *See* Purepac Br. at 34, 37. In fact, Judge Lifland addressed W-L's motion to dismiss Purepac's sham

litigation counterclaims on the grounds that W-L's infringement claims had survived Purepac's motion for summary judgment in earlier litigation. *See Warner-Lambert v. Purepac Pharm. Co.*, 2000 WL 34213890 (D.N.J. Dec. 22, 2000). Although he denied W-L's motion, he did not rule that Purepac had stated a claim of sham litigation. Rather, he ruled that "[t]he mere fact that summary judgment was denied in the 98-2749 litigation does not, *in and of itself*, preclude Purepac's counterclaims of antitrust violations." *Id.* at *6 (emphasis added).

Much has changed since 2000. As noted in W-L's opening brief, in addition to Judge Lifland's 2000 denial of plaintiff's motion for summary judgment in the earlier Purepac litigation, there have been three subsequent decisions where courts have denied Rule 11 motions and found that W-L's claims on the '476 Patent were not objectively baseless: *Warner-Lambert Co. v. Purepac Pharm. Co.*, 2003 WL 21698310 (D.N.J. May 22, 2003), in which Judge Lifland denied Purepac's motion for attorneys' fees and rejected Purepac's argument that the complaint in the '476 litigation was baseless; *Warner-Lambert Co. v. Apotex Corp.*, 2003 WL 21754948 (N.D. Ill. Jul. 28, 2003), in which Magistrate Judge Keys denied a motion for fees and Rule 11 sanctions; *Warner-Lambert v. Apotex Corp.*, 2003 WL 22887861, at *4-5 (N.D. Ill. Dec. 4, 2003), in which Judge Plunkett adopted Magistrate Judge Keys' ruling. Purepac does not and cannot dispute that these decisions were based

on the same objectively reasonable standard under Rule 11 that the *PRE* decision enunciated as the proper standard for sham litigation claims.[6]

Instead, Purepac argues that "[i]t would be improper to foreclose Purepac from taking discovery as to sham-litigation allegations" based on Judge Lifland's Rule 11 decision because "Purepac has not taken discovery on those antitrust claims" and Judge Lifland ruled "without trial or a hearing." Purepac Br. at 35. To the contrary, discovery was complete on W-L's claim of infringement and the basis for W-L's claim, the issues necessary for Judge Lifland's Rule 11 decision. No discovery is necessary on Purepac's antitrust claim because, as noted above, this Court can rule on the sham litigation claims as a matter of law. The fact that Judge Lifland found no Rule 11 violation on a full record demonstrates that the filing of the '479 Patent litigation was not objectively unreasonable.

Purepac further argues that the Court cannot rely on Magistrate Judge Keys' and Judge Plunkett's Rule 11 opinions in *Warner-Lambert Co. v. Apotex Corp.*, 2003 WL 21754948 and 2003 WL 22887861, because this Court must

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[6] Purepac cites *Sumitomo Mitsubishi Silicon Corp. v. MEMC Electronic Materials, Inc.*, 2007 WL 2318903 (N.D. Cal. Aug. 13, 2007), for the proposition that a "denial of a motion for attorneys' fees should not foreclose a sham litigation claim as a matter of law." Purepac Br. at 35. In that case, however, the earlier attorneys' fees decision did not "wholly foreclose SUMCO's current [antitrust] claims" (*id.* at *12), because it was predicated on similar but different claims, not because it was based on a different standard. Nonetheless, the court found the attorneys' fees decision "probative" and *granted* MEMC's motion to dismiss because its infringement suit was not objectively baseless.

accept Purepac's allegations and not make findings based on facts recited in other cases. *See* Purepac Br. at 36 (citing *In re Wellbutrin SR Antitrust Litig.*, 2006 WL 616292 (E.D. Pa. Mar. 9, 2006)). But that is not what W-L is seeking to have this Court do. The *Apotex* cases concerned the same allegations of infringement (albeit against a different defendant) and that court, using a Rule 11 standard, ruled as a matter of law that the claim was not "baseless." This Court may rely on this persuasive precedent to conclude that W-L's identical infringement claim against Purepac also was not objectively baseless. *See PRE*, 508 U.S. at 65 (using Rule 11 standard as measure for reasonableness).[7]

Similarly, with respect to the '479 Patent litigation, Purepac argues that "W-L did not have an objective basis for believing that Purepac would induce infringement" by inducing doctors to prescribe gabapentin for neurodegenerative diseases, an unapproved use covered by the '479 Patent. Purepac Br. at 36-37. But the language of the Hatch-Waxman statute expressly provided that "[i]t shall be an act of infringement to submit . . . an [ANDA] for a drug . . . the use of which

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[7] Purepac attempts to distinguish *Q-Pharma, Inc. v. Andrew Jergens Corp.*, 360 F.3d 1295 (Fed. Cir. 2004), on the basis that "the antitrust claimant had already taken discovery on its sham-litigation claim. *Id.* at 1298-99." Purepac Br. at n.10. Contrary to Purepac's statement, the *Q-Pharma* court actually "*determined as a matter of law* that Q-Pharma's decision to proceed with the lawsuit was not 'objectively baseless.'" *Id.* at 1299 (emphasis added). The Federal Circuit also denied any further discovery under Rule 56(f) because the "proposed discovery would only have been relevant to Q-Pharma's subjective motivation and there would not have altered the court's determination." *Id.* at 1306-1306.

is claimed in a patent . . ." and does not expressly limit "the use" to FDA-approved uses. Judge Schall wrote in his concurring opinion in *Allergan* that W-L's interpretation of that statute to permit the allegation of infringement in the '479 lawsuit was reasonable. *See* Pls. Br. at 45.

In response, Purepac "disagrees with Judge Schall's opinion" (Purepac Br. at 38) and argues that "*Allergan* is distinguishable because while Allergan submitted proof that the alleged infringer advertised and publicized off-label uses, 'Warner-Lambert was not able to present [such] evidence.'" Purepac Br. at 38. But that difference only goes to whether W-L would ultimately prevail on its claim against Purepac, not to whether it was objectively unreasonable to bring the claim in the first instance. On that key question, Judge Schall said the answer was "no."[8]

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[8] Purepac attempts to bootstrap a New Jersey common law claim for unfair competition. For the reasons stated herein with respect to its federal claims, Purepac's state law claim should also be dismissed. *See* Pls. Br. at 46-47.

CONCLUSION

For the foregoing reasons, W-L respectfully requests that the Court strike Purepac's affirmative defense of unclean hands and patent misuse and dismiss with prejudice Purepac's counterclaims for patent misuse, unclean hands, violations of the Sherman Act, and common law unfair competition.

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IN THE UNITED STATES DISTRICT COURT
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PFIZER INC., WARNER-LAMBERT COMPANY LLC, GÖDECKE GMBH and PFIZER PHARMACEUTICALS LLC, Plaintiffs, v. PUREPAC PHARMACEUTICAL CO., FAULDING INC. and ACTAVIS ELIZABETH LLC, Defendants.	VIA ELECTRONIC FILING Hon. Faith S. Hochberg, U.S.D.J. Hon. Patty Shwartz, U.S.M.J. MDL Docket No. 1384 **This Filing Applies To:** Purepac Defendants C.A. No. 00-CV-2931 (FSH) C.A. No. 00-CV-3522 (FSH) **CERTIFICATION OF SERVICE**

I, Michael C. Zogby, an attorney in the State of New Jersey, and an associate at the law firm of Drinker Biddle & Reath LLP, hereby certify that I have, on the 17th day of September 2008, caused the foregoing Reply Brief in Support of Plaintiffs' Motion to Strike Certain Affirmative

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